

114TH CONGRESS  
2D SESSION

# H. R. 4784

To increase competition in the pharmaceutical industry.

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IN THE HOUSE OF REPRESENTATIVES

MARCH 17, 2016

Mr. SCHRADER (for himself and Mr. BILIRAKIS) introduced the following bill;  
which was referred to the Committee on Energy and Commerce

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## A BILL

To increase competition in the pharmaceutical industry.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Lower Drug Costs  
5 through Competition Act”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

8 (1) As part of the Food and Drug Administra-  
9 tion’s mission to protect the public health, the Food  
10 and Drug Administration approves generic drugs  
11 that help establish competitive markets for treat-

1       ments that improve the lives of millions of patients  
2       in the United States.

3               (2) Rising health care costs, including prescrip-  
4       tion drug costs, continue to be a major concern for  
5       patients in the United States.

6               (3) Eighty-eight percent of prescription drugs  
7       dispensed in the United States, or nearly 9 out of  
8       every 10 prescriptions dispensed, are generic drugs.

9               (4) Studies suggest that generic drugs account  
10      for only 28 percent of total prescription drug spend-  
11      ing and were responsible for \$1,680,000,000,000 in  
12      estimated savings over the period of 2005 to 2014.

13              (5) Increasing generic competition can be an ef-  
14      fective way to help keep prescription drug costs low  
15      for patients, the health care system, and Federal  
16      and State government.

17              (6) While the Food and Drug Administration  
18      has made progress toward a more consistent  
19      timeline for generic drug approvals since the enact-  
20      ment of the Generic Drug User Fee Amendments of  
21      2012 (21 U.S.C. 379j–41 et seq.), a significant  
22      backlog of abbreviated new drug applications for ge-  
23      neric drugs remains.

24              (7) The sudden, aggressive price hikes for a va-  
25      riety of recently acquired off-patent drugs that have

1       been used widely for decades, for which there is no  
2       generic drug competitor, also affects access to af-  
3       fordable prescriptions for patients and the overall  
4       cost of health care in the United States.

5           (8) Improving the review of abbreviated new  
6       drug applications and the approval of generic drugs  
7       would help to improve competition and lower prices  
8       for patients.

9           (9) Establishing a clear timeframe for the Food  
10      and Drug Administration to expedite the review of  
11      certain applications for generic drugs would also  
12      help keep drug prices down and improve timely ac-  
13      cess for patients.

14   **TITLE     I—REMOVING     REGU-**  
15   **LATORY BARRIERS TO COM-**  
16   **PETITION**

17   **SEC. 101. IMPROVING GENERIC ACCESS.**

18       Section 505(j) of the Federal Food, Drug, and Cos-  
19      metic Act (21 U.S.C. 355(j)) is amended by adding at the  
20      end the following:

21       “(11)(A) The Secretary shall prioritize the review,  
22      and act not later than 180 calendar days after the date  
23      of the submission of an application, on an application that  
24      has been submitted and accepted for review under this

1 subsection, or on a supplement to such an application,  
2 that is for a drug that—

3 “(i) has been introduced into interstate com-  
4 merce by not more than one manufacturer or spon-  
5 sor, as applicable, in the last 3 months and with re-  
6 spect to which tentative approval under paragraph  
7 (5) has been granted for not more than 2 applica-  
8 tions; or

9 “(ii) has been included on the list under section  
10 506E.

11 “(B) The Secretary may expedite an inspection or re-  
12 inspection under section 704 of an establishment that pro-  
13 poses to manufacture a drug described in subparagraph  
14 (A).”.

15 **SEC. 102. REPORTING ON PENDING GENERIC DRUG APPLI-**  
16 **CATIONS.**

17 Not later than 180 calendar days after the date of  
18 enactment of this Act, and every 180 calendar days there-  
19 after until October 1, 2021, the Secretary of Health and  
20 Human Services shall submit to the Committee on Health,  
21 Education, Labor, and Pensions of the Senate, the Special  
22 Committee on Aging of the Senate, and the Committee  
23 on Energy and Commerce of the House of Representatives  
24 a report that provides—

1           (1) the number of applications that were filed  
2 under section 505(j) of the Federal Food, Drug, and  
3 Cosmetic Act (21 U.S.C. 355(j)) prior to October 1,  
4 2016, that are pending at the time the report is sub-  
5 mitted;

6           (2) the average and median total time such ap-  
7 plications have been pending;

8           (3) the number of such applications that con-  
9 tain certifications under section  
10 505(j)(2)(A)(vii)(IV) of such Act; and

11           (4) the number of such applications that are  
12 subject to priority review.

## 13           **TITLE II—INCENTIVIZING** 14           **COMPETITION**

### 15   **SEC. 201. GENERIC PRIORITY REVIEW VOUCHER.**

16           Chapter V of the Federal Food, Drug, and Cosmetic  
17 Act (21 U.S.C. 351 et seq.) is amended by inserting after  
18 section 506F the following:

#### 19   **“SEC. 506G. GENERIC PRIORITY REVIEW VOUCHER.**

20           “(a) **DEFINITIONS.**—In this section:

21           “(1) The term ‘priority review’ with respect to  
22 an application under section 505(j) means review  
23 and action by the Secretary on such application by  
24 the Secretary not later than 180 calendar days after

1 such application has been submitted and accepted  
2 for review.

3 “(2) The term ‘priority review voucher’ means  
4 a voucher for priority review for an application  
5 under section 505(j). Such voucher shall be awarded  
6 upon the approval of the application described in  
7 505(j)(11)(A), unless such application contains a  
8 certification under section 505(j)(2)(A)(vii)(IV).

9 “(b) GENERIC PRIORITY REVIEW VOUCHERS, IN  
10 GENERAL.—Beginning on October 1, 2017, the Secretary  
11 shall award a priority review voucher to the sponsor of  
12 an application described in section 505(j)(11)(A) upon—

13 “(1) approval by the Secretary of such applica-  
14 tion;

15 “(2) marketing of the drug subject to such ap-  
16 plication; and

17 “(3) determination by the Secretary that the  
18 drug has a sustained market presence.

19 “(c) TRANSFERABILITY.—

20 “(1) IN GENERAL.—The recipient of a priority  
21 review voucher under subsection (a) may transfer  
22 (including by sale) the entitlement to such voucher.  
23 There is no limit on the number of times a priority  
24 review voucher may be transferred before such  
25 voucher is used.

1           “(2) NOTIFICATION TO THE SECRETARY.—

2           Each person to whom a voucher is transferred shall  
3           notify the Secretary of such change in ownership of  
4           such voucher not later than 30 calendar days after  
5           such transfer.

6           “(d) NOTIFICATION.—The sponsor shall notify the  
7           Secretary not later than 30 calendar days prior to the sub-  
8           mission of a human drug application that is intended to  
9           be the subject of a priority review voucher, except in the  
10          case of such an application that was pending as of October  
11          1, 2017, in which case the sponsor of such pending appli-  
12          cation shall notify the Secretary not later than 30 days  
13          after the date on which such voucher is awarded.

14          “(e) FEES.—

15                 “(1) IN GENERAL.—The sponsor of an applica-  
16                 tion that is the subject of a priority review voucher  
17                 shall be subject to the fees required under sub-  
18                 chapter C of chapter VII.

19                 “(2) PRIORITY REVIEW USER FEE.—

20                         “(A) IN GENERAL.—The Secretary shall  
21                         establish a user fee program under which a  
22                         sponsor of a human drug application that is the  
23                         subject of a priority review voucher shall pay to  
24                         the Secretary a fee determined under subpara-  
25                         graph (B). Such fee shall be in addition to any

1 fee required to be submitted by the sponsor  
2 under subchapter C of chapter VII.

3 “(B) FEE AMOUNT.—The amount of the  
4 priority review user fee shall be determined  
5 each fiscal year by the Secretary, based on  
6 twice the difference between—

7 “(i) the average cost incurred by the  
8 Food and Drug Administration in the re-  
9 view of a human drug application subject  
10 to priority review under this section in the  
11 previous fiscal year; and

12 “(ii) the average cost incurred by the  
13 Food and Drug Administration in the re-  
14 view of a human drug application under  
15 section 505(j) that is not subject to pri-  
16 ority review under this section in the pre-  
17 vious fiscal year.

18 “(C) ANNUAL FEE SETTING.—The Sec-  
19 retary shall establish, before the beginning of  
20 each fiscal year beginning after September 30,  
21 2017, and in accordance with subparagraph  
22 (B), the amount of the priority review user fee  
23 for that fiscal year.

24 “(D) PAYMENT.—



1           “(i) IN GENERAL.—The priority re-  
2 view user fee required by this paragraph  
3 shall be due upon the notification by a  
4 sponsor of the intent of such sponsor to  
5 use the voucher, as specified in subsection  
6 (d). All other user fees associated with the  
7 human drug application shall be due as re-  
8 quired by the Secretary or under applicable  
9 law.

10           “(ii) COMPLETE APPLICATION.—An  
11 application described in clause (i) for  
12 which the sponsor requests the use of a  
13 priority review voucher shall be considered  
14 incomplete if the fee required by this para-  
15 graph and all other applicable user fees are  
16 not paid in accordance with the Secretary’s  
17 procedures for paying such fees.

18           “(iii) NO WAIVERS, EXEMPTIONS, RE-  
19 DUCTIONS, OR REFUNDS.—The Secretary  
20 may not grant a waiver, exemption, reduc-  
21 tion, or refund of any fees due and payable  
22 under this paragraph.

23           “(E) OFFSETTING COLLECTIONS.—Fees  
24 collected pursuant to this paragraph for any fis-  
25 cal year—

1           “(i) shall be deposited and credited as  
2           offsetting collections to the account pro-  
3           viding appropriations to the Food and  
4           Drug Administration; and

5           “(ii) shall not be collected for any fis-  
6           cal year except to the extent provided in  
7           advance in appropriations Acts.

8           “(f) CLARIFICATION.—Nothing in this section affects  
9 any period of exclusivity under this Act or the protection  
10 of any patent.

11          “(g) SUNSET.—The authority of the Secretary to  
12 carry out the generic priority review voucher program  
13 under this section shall terminate on October 1, 2021.”.

14 **SEC. 202. TROPICAL DISEASE PRODUCT APPLICATION.**

15          Section 524(a)(4)(A) of the Federal Food, Drug, and  
16 Cosmetic Act (21 U.S.C. 360n(a)(4)(A)) is amended—

17           (1) in clause (i), by striking “and”;

18           (2) in clause (ii), by adding “and” after the  
19 semicolon; and

20           (3) by adding at the end the following:

21           “(iii) that contains reports of new  
22 clinical investigations (other than bio-  
23 availability studies) essential to the ap-  
24 proval of the application and conducted or  
25 sponsored by the applicant;”.

1           **TITLE III—STUDY ON REMS**

2   **SEC. 301. STUDY ON REMS.**

3           (a) IN GENERAL.—The Comptroller General shall  
4   conduct a review of the implementation and effectiveness  
5   of section 505–1 of the Federal Food, Drug, and Cosmetic  
6   Act (21 U.S.C. 355–1) (referred to in this section as the  
7   “REMS program”), which section—

8           (1) authorizes the Secretary of Health and  
9   Human Services to require a risk evaluation and  
10   mitigation strategy (referred to in this section as  
11   “REMS”); and

12           (2) codifies and expands regulations issued by  
13   the Food and Drug Administration under which the  
14   Food and Drug Administration may impose restric-  
15   tions on distribution necessary to ensure a drug is  
16   safely used.

17           (b) CONTENTS OF STUDY.—In conducting the review  
18   under subsection (a), the Comptroller General shall exam-  
19   ine each relevant element described in subsection (c) with  
20   respect to each of the following categories:

21           (1) New drug applications under subsection (b)  
22   of section 505 of the Federal Food, Drug, and Cos-  
23   metic Act (21 U.S.C. 355(b)).

24           (2) Abbreviated new drug applications under  
25   subsection (j) of such section.

1           (3) Applications for the license of a biological  
2           product under section 351 of the Public Health  
3           Service Act (42 U.S.C. 262).

4           (4) Single, shared system REMS, as described  
5           in section 505–1(i) of the Food, Drug, and Cosmetic  
6           Act (21 U.S.C. 355–1(i)).

7           (5) Controlled substances as defined in section  
8           102 of the Controlled Substances Act (21 U.S.C.  
9           802).

10          (6) RISKMAPs or other risk management proc-  
11          esses employed by the Food and Drug Administra-  
12          tion.

13          (c) ELEMENTS UNDER REVIEW.—In conducting the  
14          review under subsection (a), the Comptroller General shall  
15          examine each of the following elements with respect to  
16          each relevant category described in subsection (b).

17               (1) For each type of application, and by year,  
18               the number of REMS required, submitted, volun-  
19               tarily submitted, modified, added, approved, or re-  
20               moved, and whether those REMS included elements  
21               to assure safe use, such as restricted distribution.

22               (2) For each type of application, the number of  
23               REMS in effect at the time of the review and the  
24               number of years that each such REMS has been in  
25               effect at such time.

1           (3) If and how the REMS program has im-  
2           proved drug safety, as compared to the time before  
3           the REMS program became effective, and how the  
4           Food and Drug Administration tracks such improve-  
5           ments.

6           (4) The burdens associated with REMS, includ-  
7           ing burdens on patients, health care providers, ge-  
8           neric drug manufacturers, brand drug manufactur-  
9           ers, pharmacies, and wholesale distributors.

10          (5) In the case of a REMS program for a drug  
11          containing a controlled substance, the coordination  
12          between the Food and Drug Administration and the  
13          Drug Enforcement Administration.

14          (6) The effect of additional risk mitigation  
15          strategies, including non-REMS restricted distribu-  
16          tion systems, imposed by companies outside of what  
17          is required under the REMS program.

18          (7) The standards and policies applied by the  
19          Food and Drug Administration to require, modify,  
20          add, or remove a REMS, and how those standards  
21          and policies have changed since the REMS program  
22          became effective.

23          (8) The effect of REMS programs and addi-  
24          tional risk mitigation strategies, including non-

1 REIMS restricted distribution systems, on generic  
2 entry into the marketplace.

3 (9) The effect of REIMS programs and addi-  
4 tional risk mitigation strategies, including non-  
5 REIMS restricted distribution systems, on pharma-  
6 ceutical prices.

7 (d) REPORT.—Not later than May 1, 2017, the  
8 Comptroller General shall submit a report to the Com-  
9 mittee on Health, Education, Labor, and Pensions of the  
10 Senate, the Special Committee on Aging of the Senate,  
11 and the Committee on Energy and Commerce of the  
12 House of Representatives, containing the results of the re-  
13 view described in this section.

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